REMARKS/ARGUMENTS

The Office Action mailed January 10, 2008 has been received and carefully noted. Claims 61-68 and 79-83 were examined and rejected. Claims 1-60 and 69-78 have been previously cancelled.

Applicants amend no claims.

Applicants respectfully request reconsideration of claims 61-68 and claims 70-83 in view of the following remarks.

Claim Rejections – 35 U.S.C. § 102

Claims 61, 63, 68, 79, 80 and 82 are rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 6,045,531 to Davis (Davis). It is axiomatic that to be anticipated, every limitation of the claim must be disclosed in a single reference.

Applicants respectfully disagree with the rejection above for at least the reason that the cited reference does not disclose a method including inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest; and perfusing a blood and/or a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61.

Davis describes catheters 10 and 100, and methods of use thereof (see col. 1, line 60 through col. 3, line 64). Specifically, Davis describes advancing catheter 100 downwards into aorta 12 such that the distal end of the catheter is positioned in the aortic base 24, and then perfusing aorta 12 using large lumen 124 to provide oxygenating blood dispensed via proximal openings 110 and distal opening 104 (see col. 7, line 59 through col. 8, line 5). Balloon 114 is then inflated to engage the inner wall of aorta 12, and then balloon 160 is inflated occlude large lumen 124 to isolate distal opening 104 from proximal openings 110, while oxygenating blood supplied by lumen 124 continues to perfuse from proximal openings 110 into ascending aorta 12 (see col. 8, lines 5-16). In the descriptions above, oxygenating blood is provided by lumen 124 to both proximal openings 110 and distal opening 104; or to only openings 110 (e.g., when balloon 160 is inflated).

Moreover, according to Davis, after arresting the heart, the heart may be

restarted by deflating balloon 160 to infuse blood from lumen 124 through distal opening 104 to infuse the coronaries at aortic base 24 (see col. 8, lines 25-33). In this description, the oxygenated blood is again provided by lumen 124.

Consequently, the Patent Office has not identified and Applicants are unable to identify any disclosure in Davis of a method including inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest; and perfusing a blood and/or treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61. Thus, Applicants respectfully request that the Patent Office withdraw the rejection of claim 61.

Next, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 63 for at least the reason that Davis does not disclose a method wherein inflating includes inflating the balloon for a first period of time and perfusing includes deflating the balloon for a second period of time; and at least one more repetition of inflating, infusing, and deflating as required by claim 63. As noted above for claim 61, Davis teaches inflating and deflating balloon 160 to selectively occlude or open large inner lumen 124 (see col. 7, lines 51-57). However, balloon 160 is not a balloon that can be inflated to a diameter "that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest," as required by claim 61 from which claim 63 depends. Moreover, Davis does not teach repeating arresting the patients heart and restarting the patient's heart (e.g., occluding, infusing and perfusing). Thus, the Patent Office has not identified and Applicants are unable to identify any disclosure in Davis of the above noted limitations of claim 63. Hence, Applicants respectfully request the Patent Office withdraw the rejection of claim 63 for this additional reason.

Next, in addition to the dependence upon claim 61, Applicants respectfully disagree with the rejection of claim 82 for at least the reason that Davis does not disclose perfusing a blood flow from a location in the blood vessel proximal to the balloon to a location in the region of interest distal to the balloon, as required by claim 82. As noted above for claim 61, Davis teaches that blood supplied by lumen 124 is advanced through openings 110 and/or opening 104. However, there is no description in Davis of perfusing a blood flow from a location in the blood vessel proximal to the balloon to

a location distal to the balloon, as required by claim 82. Hence, for at least this additional reason, Applicants respectfully request withdrawal of the rejection above of claim 82.

Claim Rejections – 35 U.S.C. § 103

Claims 62 and 81 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Davis in view of U.S. Application Publication No. 2002/0049402 to Peacock et al. (Peacock). Claims 64-66 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of U.S. Patent No. 5,370,617to Sahota (Sahota). Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (US Patent No. 6,045,531) in view of U.S. Patent No. 6,805,860 to Alt (Alt). For a claim to be obvious, each limitation of the claim must be taught or suggested by at least one properly combined reference. Furthermore, the combination of elements must be "more than a predictable use of prior art elements according to their established functions." (see KSR International Company v. Teleflex Inc., No. 04-1350 (Supreme Court, April 30, 2007)).

Applicants respectfully disagree with the rejection above for at least the reason that the other cited references do not cure the deficiencies of Davis noted above for claim 61, from which the above noted claims depend.

For example, Peacock describes holes through the exterior surface of a cannula (see FIGS. 1a and 1b, holes 4 and 5). However, the Patent Office has not identified and Applicants are unable to find any teaching in Peacock of the above-noted limitations of claim 61.

Furthermore, Sahota teaches dilatation catheters for use in administering treatments to relieve stenotic regions within a body lumen while maintaining blood flow past the dilatation balloons (see Abstract). Moreover, Sahota teaches both a perfusing lumen 15 and a guidewire lumen 17, to maintain a steady flow of blood; and having ports 55 and 57 that communicate blood between the two lumens. (see FIG. 4; and col. 2, lines 14-40). Specifically, Sahota teaches maintaining a steady flow of blood using blood channels through both a perfusing lumen 15 and a guidewire lumen 17. (see col. 3, lines 17-37).

However, the Patent Office has not identified and Applicants are unable to identify any teaching in Sahota of inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood

vessel to occlude the blood vessel at the region of interest; and perfusing a blood and/or a treatment agent flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon, as required by claim 61. In other words, the combination of Sahota and Davis does not teach the above noted limitations since the perfusion of Sahota can not be stopped to occlude the vessel. (see ports 54 and 56 of perfusing lumen 15 in FIG. 4). For example, guide wire 16 of Sahota may occlude cannula 17, but does not occlude perfusing lumen 15 (e.g., see FIG. 4). Thus, the flow of blood continues through opening 54 through lumen 15 and out of opening 56 (see FIG. 4). On the other hand, according to claim 61, for example and without limitation thereto, a blood vessel can be occluded, treated, perfused, occluded, treated, perfused, etc. without removing the cannula and without deflating the occlusion balloon.

Moreover, the combination of Sahota and Davis is improper. It can be appreciated that the primary purpose of Sahota is to avoid occlusion or reduction of blood flow by maximizing the flow of blood past the expanded balloon (see col. 1 Lines 52-63). Thus, Sahota teaches against occluding as claimed, and can not be properly combined with a reference to teach such a practice.

Applicants also note that the primary purpose of Davis is to use balloon 160 to occlude cannula 124 to control the flow of oxygenated blood from cannula 124 through opening 104 and openings 110, where balloon 160 is located between opening 104 and openings 110 (see FIGS. 5-6). Hence, combining guide wire 116 of Sahota with cannula 124 of Davis would provide an embodiment that could not function properly as required by Davis. Specifically, the guide wire of Sahota would plug up and discontinue the flow of oxygenated blood through cannula 124 of Davis, thus denying the patient's body of oxygen and killing the patient. Consequently, a practitioner would not attempt to combine the teachings as asserted by the Patent Office.

Similarly, Alt fails to cure the deficiencies of Davis and Sahota noted above for claim 61. Alt teaches injection of progenitor cells (see col. 13, lines 27-31). However, the Patent Office has not identified and Applicants are unable to identify any teaching in Alt of the above noted limitations, as required by claim 61.

Dependent Claims

Any dependent claims not mentioned here and are asserted as patentable over the cited references for at least the reasons explained herein for allowing their base claims, in addition to any additional limitations of those dependent claims.

Hence, for at least the reasons above, Applicants respectfully request withdrawal of all the rejections above.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes a telephone conference would be useful in moving the case forward, he is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted to the United States Patent and Trademark Office electronically via EFS Web on the date shown below.

Robert Fiore — 3/14/08 Date